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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,473	01/21/2004	John C. Rueter	P0011409.00	4388

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER	
GEDEON, BRIAN T	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,473	RUETER, JOHN C.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment after non-final filed 19 December 2008. Claims 1-24 are pending, wherein claims 3, 11, 14, and 22 are amended.

Response to Arguments

2. Applicant's arguments, see Remarks, filed 19 December 2008, with respect to the rejection(s) of claim(s) 1, 6, 11, 12, 16, 21, and 22 under 35 U.S.C. 102 (b) as being anticipated by Jorgenson et al. (US Patent no. 6,317,633) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 U.S.C. 102 (e) as being unpatentable under Levine et al. (US Patent no. 7,308,310).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 6, 11, 12, 16, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine et al. (US Patent no. 7,308,310).

In regard to claims 1, 6, 11, 12, 16, and 22, Levine et al. describe an implantable cardiac stimulation device for managing capture and lead impedance. The device includes a pulse generator 70, 72, a physiological sensor 108, programmable microcontroller 60, impedance measurement circuit 112, and associated electrodes 40, 41, 42, 44, 46, 48, 52, 54, 56, and 58. The device operates by monitoring for an indicator of a likely increase in pacing/capture threshold by measuring the impedance of the pacing lead, see figure 3 and col 11 line 55 - col 12 line 9. An increase in the impedance of the pacing lead is taught by Levine et al. to be an indicator of a likely increase in the capture threshold. If the impedance is determined to be in abnormal range, subroutine 128, figure 3, is implemented. The subroutine 128 can consist of the algorithm in figure 6 wherein, the output of the device is increased in step 184 to ensure that capture occurs in response to the abnormal lead impedance, col 14 lines 4-17. The occurrence of the increased output of the device in figure 6 is considered to be an increase in a safety factor in response to detection of an indicator that the pacing/capture threshold likely increased, since the objective of the increased output is to ensure capture occurs due to the abnormal impedance of the pacing lead requiring higher signal output to achieve capture.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-5, 13-15, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (US Patent no. 7,308,310) in view of Schloss (US Patent no. 6,456,882 – provided on Applicant's IDS dated 5/12/2005).

In regard to claims 2-5 and 13-15, Levine et al. substantially describe the invention as claimed except for the setting time interval and restoring safety factors to a programmed variable. Schloss describes an implantable medical device 700 comprising: a pulse generator 80, for delivering pacing pulses; at least one electrode 75 and 77, in electrical communication with the pulse generator for delivering the pacing pulses to cardiac tissue; and a microprocessor 22 for controlling the pulse generator, receiving sensed data from the at least one electrode, wherein the sensed data includes an indicator, col 12 lines 27-30, of increased pacing threshold, and increasing a safety factor, col 12 lines 25-27, used for setting the pacing pulse energy delivered by the pulse generator when the indicator of increased pacing threshold is detected, also see figure 3. Schloss teaches setting a time interval during which the increased safety factor is maintained; and restoring the safety factor to a programmed value after the time interval has expired, col 3 lines 42-47, and setting a time interval during which the increased safety factor is maintained; and restoring the safety factor to a programmed value after the time interval has expired, col 3 lines 37-41. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Levine et al. with the teaching of Schloss in order to determine if

the safety margin adjustment criteria has been met, and that excess energy is not expended if deemed not necessary by having a high safety margin.

7. Claims 6-10 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (US Patent no. 7,308,310) in view of Sloman et al. (EP 1 136 098 A2 – provided on Applicant's IDS dated 5/12/2005).

In regard to claims 6-10 and 16-20, Levine et al. substantially describes the invention as claimed except for the indicators of increased pacing threshold. Sloman et al. describes an implantable medical device 10 comprising: a pulse generator 70 and 72, col 7 lines 40-45, for delivering pacing pulses; at least one electrode 26, 27, and 28, see fig. 1 and col 6 lines 5-8, in electrical communication with the pulse generator for delivering the pacing pulses to cardiac tissue; and a microprocessor 60, col 7lines 17-18, for controlling the pulse generator, receiving sensed data from the at least one electrode, wherein the sensed data includes an indicator, col 17 line 28, of increased pacing threshold, and increasing a safety factor, col 17 lines 19-22, used for setting the pacing pulse energy delivered by the pulse generator when the indicator of increased pacing threshold is detected. Sloman et al. have an impedance sensor 112, an arrhythmia detector, col 11 lines 25-47, a refractory period detector, col 8 lines 1-2, and/or change in pacing/stimulation modes, col 12 lines 4-15. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Levine et al. with the teachings of Sloman et al. since Sloman et al. discloses means and methods for detecting various indicators indicating an increased threshold.

Conclusion

8. In view of the new grounds of Rejection under Levine et al., this action is made **NON-FINAL**.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

Carl H. Layno
Examiner
Art Unit 3766

/B. T. G./
Examiner, Art Unit 3766
27 March 2009